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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,928	03/23/2005	Marc Hubert Mercken	PRD-0032-USPCT1	4646
27777 7590 04/17/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER WANG, CHANG YU	
			ART UNIT	PAPER NUMBER
			1649	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/17/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/528,928

Applicant(s)

MERCKEN ET AL.

Examiner

Chang-Yu Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/1/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 10 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-9, 11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed February 1, 2007 is acknowledged. Claims 12-13 are cancelled.
2. Claims 1-11, 14-16 are pending and under examination in this office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.
4. Applicant's arguments filed on February 1, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

5. The objection to the specification because of lack of sequence identifiers (p. 19) is maintained. Appropriate correction is required.

Claim Rejections/Objections Withdrawn

6. The objection to claims 6 and 7 due to typographical error is withdrawn in response to Applicant's amendment to the claims.

The rejection of claims 14,16 under 35 U.S.C. §112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is withdrawn in response to Applicant's amendment to the claims.

The rejection of claims 13 and 14 under 35 U.S.C. 101 and 112 2nd paragraph because of the recitation "a use" is withdrawn in response to Applicant's amendment to the claim and cancellation of claim 13.

The rejection of claim 16 under 35 U.S.C. 112 second paragraph for being indefinite because of the recitation of carrier means is withdrawn in response to Applicant's amendment to the claim.

The rejection of Claim 13 under 35 U.S.C. 102 (b) for being anticipated by Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383), Pirttila et al. (J. Neurol Sci. 1994 Dec 1; 127:90-5), WO0162801 (as in IDS submitted on Mar 23, 2005) and Naslund et al (as in IDS submitted on Mar 23, 2005) is moot because the claim is cancelled.

The rejection of claim 13 under 35 U.S.C. 103(a) for being unpatentable over Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) in view of Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383 as cited in the previous office action) and WO0162801 (as in IDS submitted on Mar 23, 2005 and cited in the previous office action) is moot because the claim is cancelled.

Claim Rejections/Objections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The rejection of claims 1-5, 8, 9, 11 and 14-16 under 35 U.S.C. 102 (b) for being anticipated by Walker et al (J. Neuropathol. Exp. Neurol. 1994 Jul. 53: 377-383), Pirttila et al. (J. Neurol Sci. 1994 Dec 1; 127:90-5), WO0162801 (as in IDS submitted on Mar 23, 2005) and Naslund et al (as in IDS submitted on Mar 23, 2005) is maintained for the reasons set forth in the previous office action and restated herein.

Applicant argues that as discussed in the response filed on July 14, 2006, none of the references cited teach an antibody that is specific for the Ab11-x peptides.

Applicant's arguments have been fully considered but they are not persuasive.

8. In response, the art antibodies raised against A β 1-16 and A β 13-28 immunogens can bind to the epitopes of A β 11-x as evidenced by Huse et al (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284). Huse et al. teach that BNT77, a monoclonal antibody against amino acids 11-16 of A β , can recognize both full-length and N-terminal truncated species of A β . Since an antibody against 11-16 can recognize an N-terminal truncation, the examiner asserts that an antibody against 1-16 could also recognize the N-terminal truncated A β including A β 11-x. In addition, Huse et al. teaches that 4G8, a monoclonal antibody against amino acids of 17-24 of A β , can detect A β 1-40, A β 11-40, A β 1-34 and A β 11-34 species of A β . Thus, an antibody against 13-28 would have the same properties. The antibody, 10D5 against A β 1-16 as disclosed by Walker et al., the antibodies, 6E10 against A β 1-16 and 4G8 against 13-28, as disclosed by Pirttila and the

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antibody, m266 against A β 13-28, as disclosed by WO0162801 do bind to A β 11-x as shown in Huse et al. and WO0162801. Applicant has provided no showing that the antibodies in the art have characteristics different from those specified by Applicant and do not in fact bind to the same epitopes.

9. The rejection claims 1-2, 5, 8, 14-16 under 35 U.S.C. 102 (b) for being anticipated by Solomon et al. (Proc. Natl. Acad. Sci. USA. 1996. 93: 452-455) is maintained for reasons of record in the previous office action. The rejection of claims 1-2, 5, 8, 14-16 under 35 U.S.C. 102 (a) for being anticipated by Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) is maintained for reasons of record in the previous office action.

Applicant argues that Solomon et al. and Huse et al. do not teach the claimed antibody, which is directed to a monoclonal antibody that specifically recognizes A β 11-x. Applicant's arguments have been fully considered but they are not persuasive.

10. In response, the examiner asserts that art antibodies can recognize A β 11-x. Solomon et al. teach two monoclonal antibodies AMY-33 and 6F/3D raised against amino acids 1-28 and 8-17 of A β respectively. The antibodies raised against aa 1-28 and 8-17 would inherently recognize A β 11-x because the amino acid sequence of the immunogens (5-7 amino acids of A β 11-x) for the instant antibodies are encompassed in the sequences of amino acids 1-28 and 8-17 of A β . For the same reason, the antibody BNT77 taught by Huse et al. was raised against amino acids 11-16 of A β , thus it can

recognize both full-length and N-terminal truncated species of A β . Since an antibody against 11-16 can recognize an N-terminal truncation, the examiner asserts that an antibody against 1-16 could also recognize the N-terminal truncated A β including A β 11-x. In addition, Huse et al. teaches that 4G8, a monoclonal antibody against amino acids of 17-24 of A β , can detect A β 1-40, A β 11-40, A β 1-34 and A β 11-34 species of A β . Thus, the antibodies taught by Huse et al. can recognize A β 11-x because A β 11-x encompasses A β 11-40 and A β 11-34.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. The rejection of claims 1-5, 8, 9, 11 and 14-16 under 35 U.S.C. 103(a) for being unpatentable over Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) in view of Walker et al (J. Neuropathol. Exp. Neurol. 1994 Jul. 53: 377-383 as cited in the

previous office action) and WO0162801 (as in IDS submitted on Mar 23, 2005 and cited in the previous office action) is maintained for reason of record in the previous office action.

Applicant argues that the combined references do not disclose or suggest the claimed antibodies specific for A β 11-x peptides. Applicant's arguments have been fully considered but they are not persuasive.

12. In response, for the reasons as discussed above in the section of the rejection under USC 35 102, the antibodies disclosed by Huse et al., Walker et al. and WO0162801 do recognize A β 11-x. In addition, WO0162801 also teaches a method of detection of A β in the brain tissue and CSF of Alzheimer's disease patients using labeled antibodies by electrophoresis or ELISA (see p.26, examples 1-2; p. 30, example 6). Thus, It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to use the antibody raised against A β 11-16 or use the antibody that can recognize A β 11-x to detect A β 11-x in Alzheimer's disease because the level of A β 11-40/42 has been shown increased in AD patients. The person of ordinary skill in the art would have been motivated and have expected success in using an antibody that recognize A β 11-x to detect diseases associated A β formation because the antibody against A β 11-16 is able to detect A β 11-40/42 in AD brains.

Conclusion

Allowable Subject Matter

13. Claim 6 is objected to as being dependent upon a rejected base claim; i.e. claim1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7 and 10 are allowed.

Claims 1-5, 8-9, 11 and 14-16 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
April 2, 2007


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER